Subject: Science in the Administrative Process
Posted by Reeve Bull (Staff) on Thu, 13 Oct 2011 15:07:48 GMT
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Welcome to the forum for the Science in the Administrative Process project. On this forum, members of the Administrative Conference's Committee on Regulation will discuss research that Professor Wendy Wagner (University of Texas Law School) has conducted for the Science in the Administrative Process project. Members of the public are also invited to submit comments on Professor Wagner's research generally and on other comments submitted to the forum.

The forum is now available for the posting of comments. It will remain available until December 15 at the latest. If the discussion is to conclude prior to December 15, the Conference will announce the closing date at least one week in advance on this forum and on the Science in the Administrative Process project page on the Conference's website (www.acus.gov).

Please find attached to this posting an outline describing Professor Wendy Wagner's research plan for the Science in the Administrative Process project. Committee members and members of the public can discuss this proposed research, as well as any other issue relating to the Science in the Administrative Process project, in the comments.

Should you have any questions about the use of this forum, please do not hesitate to contact Administrative Conference Attorney Advisor Reeve T. Bull at (202) 480-2083 or rbull@acus.gov. We look forward to hearing your thoughts in this discussion thread.

File Attachments
1) COR Science Project Wagner outline 10-31-11.pdf, downloaded 64994 times

Subject: Re: Science in the Administrative Process
Posted by Jonathan Siegel (Staff) on Wed, 02 Nov 2011 13:34:35 GMT
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Welcome, everyone, to the ACUS forum. I am looking forward to participating in this discussion among committee members, staff, our consultant, and the public. I hope that this new and innovative method of conducting a committee meeting will lead to a productive discussion of Professor Wagner's project outline and that it will improve the project.

Subject: Re: Science in the Administrative Process
Posted by Jonathan Siegel (Staff) on Mon, 07 Nov 2011 15:48:19 GMT
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To get our discussion started, perhaps it would be useful to recall our prior, face-to-face committee meeting at which the committee discussed Professor Wagner's original outline for the

project. The committee's view was that the outline was too broad and covered too many topics. The committee recommended that Professor Wagner narrow the focus of the project.

In response, Professor Wagner's revised outline focuses on "strengthening internal agency processes for communicating how it uses science for regulation." Wendy, could you comment on the reasons that led you to choose this focus for the project?

Subject: Re: Science in the Administrative Process
Posted by Wendy Wagner (ACUS) on Mon, 07 Nov 2011 18:01:20 GMT
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Thanks for kicking this discussion off, Jon.

The focus of the study -- stated in a few words -- is to assess the transparency of the agencies' use of science, primarily in informal rulemakings. The lack of transparency is a problem raised in the recent NAS Formaldehyde Report and referenced in both President Obama's initial letter and in OSTP's subsequent memorandum on improving the agencies' use of science. This particular problem was also referenced by several committee members and public commenters during our meeting last May.

The topic seems to be a good starting point for a more sustained, graduated exploration of science in the regulatory state. Understanding how an agency is using science in a rulemaking is a critical first step to ensuring productive oversight by stakeholders, the courts, and political processes. Assessing how an agency explicates its use of science also illuminates whether the agency is making the best use of the available information, including internal studies by agency scientists. This topic will even provide preliminary information about how and when an agency elects to use science advisory boards, external peer review, or other intermediate mechanisms of scientific review as part of its rulemaking process. For a fuller discussion of these and other justifications, see pages 2-4 of the outline.

The study will focus on four agencies in particular -- EPA, FDA, NRC, and DOI. The research will consist of interviews with agency staff, the collection of any and all records on the topic, and the integration of several case studies.

I look forward to your comments on this project.

Subject: Re: Science in the Administrative Process
Posted by gillian metzger on Thu, 10 Nov 2011 14:36:11 GMT
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Wendy --

Thanks for the additional explanation and the write-up. I missed the initial meeting on the project

but it sounds like you have tried to narrowed the project to focus on one important internal dimension of agency use of science.

I had two follow up questions. First, you mention in passing some possible payoffs for interagency coordination by more expeditious identification of points of disagreement(#4, p. 4 of the draft outline). And interagency coordination is the subject of some of your proposed questions. But I'd welcome further explanation of how you see transparency contributing to better inter-agency coordination, and particularly how this might lead to more expeditious identification of disagreements as you suggest. Part of my confusion here is that in proposed reforms you stress having agencies write up and include the statement of their use of science in the preamble of a proposed rule, which seems late for purposes of encouraging interagency coordination.

Second, do you expect to explore the relationship between transparency practices and other internal features of the agency's use of science, such as the role science advisors play, the form of internal rulemaking process, the role scientific staff play in that process, and--related to my first point--use of scientific expertise in other agencies? My intuition would be that how the rulemaking process is structured may well play a role in transparency and changes in such structures might prove quite useful in producing greater transparency. It also seems like this could be a way to start generating some information about the effect of such internal structures on agencies' use of science generally. But I didn't see questions that seems geared to identifying how such internal structures were used by the agency, and wasn't sure whether you saw this more as a topic for future work investigatning the impact of such structures generally.

Gillian

Subject: Re: Science in the Administrative Process
Posted by Peter Strauss (ACUS) on Mon, 14 Nov 2011 21:09:35 GMT
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Wendy --

Let me add a couple of thoughts to Gillian's.

1) As you remark, "science" covers a multitude of possibilities. In his short book, "The Honest Broker," Roger Pielke, Jr. valuably distinguishes between the kinds of issues that can be appropriately resolved by reliable inquiry into observable facts (is a tornado approaching?), "tornado science," and others that cannot, "abortion science." Then there are soft sciences and hard sciences, physics and psychology. It would be helpful to be clear which you are addressing and perhaps, as well, to be clearer than in my impression the proposal now is about the difference between what is conventionally described as risk/science assessment and risk/science management. My impression is that you are addressing only the former, and that part of the challenge lies in getting staff to be transparent about the limits on what risk/science assessment can identify. The uncertainty range that NRC staff called the area for "engineering judgment" is part of what needs to be -- and may be most difficult to get -- acknowledged.

2) All four of your target agencies are, appropriately in my judgment, largely in the hard science business, although some things they might consider (e.g., EPA or NRC on public risk perception

as an arguable basis for priority choices) are decidedly on the "soft" side. For starters, at least, you might be clear that your focus is on staff approaches to "tornado science" and its uncertainties plus, perhaps, the accurate identification for decisionmakers of areas that "science," as such, is unlikely to resolve (though it might help to clarify).

3) The Advisory Committee on Reactor Safeguards at NRC (http://www.nrc.gov/about-nrc/regulatory/advisory/acrs.html) and the Clean Air Science Advisory Council in EPA (http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASA C) (also NIOSH in relation to OSHA) are congressionally chosen approaches at least ostensibly created to produce honest, expert, and transparent hard science advice. In my judgment such institutions ought to be a part of your inquiry, and some of their members among those you interview.

4) Were you to submit your interview protocol in writing, in my judgment (recalling how such things were handled at NRC in what were probably easier times) you'd get nothing of real value back. Look at documents if you can, but I hope you will be doing interviews viva voce -- with whatever assurances of confidentiality you can provide. And in those interviews I would try to probe the question, how much hands-on your interviewees perceive there is by "management" of their scientific inquiries/judgments. At NRC the squelching of staff views by intermediate staff managers led directly to the first Indian Point hullaballoo. Your questions don't directly ask about that; shouldn't they?

You might think to provide the Formaldehyde report in advance of interviews, saying it suggests at least some of the questions you hope to talk about.

I'm attaching a book chapter I wrote a couple of years ago on "Possible Controls over the Bending of Regulatory Science," whose profound debt to your prior work with Tom McGarity you will quickly appreciate, in the hope it might prove useful to you. (The book is Gordon Anthony et al., Eds, Values in Global Administrative Law (Hart 2011).

Subject: Re: Science in the Administrative Process
Posted by Wendy Wagner (ACUS) on Tue, 15 Nov 2011 18:16:07 GMT
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Gillian and Peter,

Thanks for your terrific comments and questions.

1. As you both intuit, various internal agency processes are emerging in the course of the study that appear to facilitate heightened transparency of the role that scientific information is playing in the decision-making process. For example, I've learned that the NAAQS process includes a number of innovative features for integrating science into the regulatory process that go well beyond the use of science advisory boards like CASAC. Indeed, the identification of these unique, science-based processes is likely to form the basis for at least one set of recommendations. This process-focus of the study then ties into Gillian's first question. More elaborate internal agency processes for scientific fact-finding, when done properly, seem capable of facilitating better interagency coordination much earlier in the process, well before the NPRM.

2. Peter's comment urging me to be more explicit in identifying the type of science under study is also quite helpful. I now imagine a short introductory section that directly responds to his questions. In terms of my answers, though, while the study does focus primarily on natural (rather than social) sciences, the science-based regulatory projects under study (e.g., endangered species decisions, nuclear reactor safety, pesticide licensing, and food regulation) include both risk assessment and risk management decisions that are often comingled. Regardless of what I find, however, ultimately trying to discuss the features of the science-policy under study in an introductory section may be a valuable contribution in its own right.

3. The interview protocol has served only as an abstract checklist and I agree that it is incomplete and won't get at many underlying problems in the agencies. In truth, I have tried to engage each interviewee on his/her own turf and press for information both on successes and problems, although I haven't had much luck in learning about the problems. (In early interviews I mistakenly promised confidentiality which I understand is not possible/recommended for ACUS studies; yet even in those confidential interviews, I did not get very far on the problem development side). Of course interest groups are happy to fill in the gaps in identifying problems with agency's science-based rulemakings, but their perspective is not comprehensive. In short, any tips you have for extracting negative information out of agency employees would be great. Sharing the NAS formaldehyde report in advance of the interview (at least the last chapter) is a terrific idea, by the way, and I will definitely do that in the future.

Thank you again for taking the time to offer such thoughtful comments. And thank you Peter for attaching your article, although I am afraid I will need another ACUS tutorial to figure out how to access it. If you have further ideas or reactions, please send them along.

All the best, Wendy

Subject: Re: Science in the Administrative Process
Posted by Reeve Bull (Staff) on Tue, 15 Nov 2011 18:48:46 GMT
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Please see the attached book chapter by Professor Strauss.

File Attachments
1) Ch6 Strauss.PDF, downloaded 62828 times

Subject: Re: Science in the Administrative Process
Posted by Peter Strauss (ACUS) on Tue, 15 Nov 2011 19:01:38 GMT
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One way to get negative indicators might be to interview past and present ACRS and CASAC members about their perceived successes and failures in transmitting science to NRC and EPA staff and, ultimately, the Commission and the Administrator. For an old story of the problem, look for the Senate hearings in January or February of 1976 into Robert Pollard's accusations of safety

issues at Indian Point, that had been sat upon at the staff level. An early Commission press release is here, pbadupws.nrc.gov/docs/ML1115/ML111590343.pdf, and I have tried to attach it; barriers to staff-Commission communication were an important element of post-Three-Mile_island analysis. See the Report of the Commission on the Accident at Three Mile Island and Shulman, 56 Notre Dame L.Rev. 351 (1981).

File Attachments

1) Pollard press release.pdf, downloaded 62649 times

Subject: Re: Science in the Administrative Process
Posted by Wendy Wagner (ACUS) on Tue, 15 Nov 2011 19:10:31 GMT
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Terrific. Thanks! NRC now has a dissenting scientist policy (called the differing professionals program) that I suspect was developed in response to this type of staff suppression. It is tough to know whether other managerial/bureaucratic pressures nevertheless squelch dissenting scientists, even with this policy in place. Do you have any insights on that?

Subject: Re: Science in the Administrative Process
Posted by Peter Strauss (ACUS) on Tue, 15 Nov 2011 19:16:20 GMT
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I didn't know about this policy and share your suspicions. Do/should other agencies have similar, essentially whistleblower regulations? As to its success, I have no information; and, that could be a question to pursue in talking with NRC people. How often has it been invoked? Have situations in which it could have been, but was not, invoked come to light? With what follow-up?

Subject: Re: Science in the Administrative Process
Posted by Susan Dudley (ACUS) on Tue, 22 Nov 2011 20:07:57 GMT
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Thank you Wendy. Recommendations for making more transparent how agencies use science to inform regulation would be worthwhile.

I'll echo Peter's request for more clarity regarding what you're defining as science. Your response recognizes that, for the areas you've selected, risk assessment and risk management are often "comingled," which I think needs more examination in your study. Greater transparency in the science underpinning regulatory decisions demands a clear distinction between science and policy judgments. As the Bipartisan Policy Center's 2009 report stated: "A critical goal of any new procedures for establishing regulatory policy must be to clarify which aspects of a regulatory issue are matters of science and which are matters of policy (e.g., economics or ethics)." (BPC, 11) http://www.bipartisanpolicy.org/library/report/science-polic y-project-final-report

Susan

Subject: Re: Science in the Administrative Process
Posted by Wendy Wagner (ACUS) on Tue, 22 Nov 2011 21:24:50 GMT
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Thanks for your comment, Susan. I'll do my best to draw distinctions between science and other forms of knowledge and judgment in this new, introductory section I reference above. Of course one must keep in mind that many (indeed most) folks working in science-policy studies believe that one cannot separate science from policy in a coherent way, so whatever I do produce will please some and annoy others. Still, I agree it will be very helpful to set out that background and will be sure to include it in the report.

If you have any sources you think I should read on this score, please feel free to pass them along. Thanks again!

Subject: Re: Science in the Administrative Process
Posted by Richard B. Belzer on Wed, 23 Nov 2011 18:09:23 GMT
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I'm going to play catch-up here, reading and responding to several of the comments posted so far.

"The focus of the study -- stated in a few words -- is to assess the transparency of the agencies' use of science, primarily in informal rulemakings. The lack of transparency is a problem raised in the recent NAS Formaldehyde Report and referenced in both President Obama's initial letter and in OSTP's subsequent memorandum on improving the agencies' use of science."

This is certainly a challenging task. Reading your outline, however, I am confused about the research method. Focusing on 4 agencies many be sensible given budget constraints, but it is important to recognize up front that you will not be able to draw any generalizations based on such a sample.

Moreover, you say you are "seeking relevant documents from within the agencies," conducting "interviews with agency staff (past and present) and knowledgeable stakeholders," and relying "where appropriate, on other government-related studies by NAS, OTA, GAO, and the general literature." Each of these approaches has significant limitations.

To be concrete, you can seek "relevant documents" all you want, but there is hardly any reason to be confident that such documents exist; that if they exist you will obtain them, given their almost certain protection from disclosure; or that any documents you do obtain will be representative and not self-serving. How will you deal with these problems? How will you test the validity of whatever document you are given?

Similarly, interviews are notoriously unreliable. You can't interview everyone, and there is no reason to believe that your sample will be representative, even for just the 4 agencies you are examining. Nor is there good reason to assume that interviewees won't behave strategically, especially because OMB's role is a central issue but OMB personnel (past or present) are not on your interview list. How do you plan to validate the responses you obtain?

Finally, relying on existing literature doesn't get you very far. Each of the organizations you cite--NAS, OTA (RIP), and GAO all have their own perspectives and biases, often resulting from disparate charges that were the foundation of their work, and limited access to the internal documents that you are seeking. At best, the existing literature can generate hypotheses for testing, and of course, many of these hypotheses will be impractical or impossible to test.

You also say:

"Understanding how an agency is using science in a rulemaking is a critical first step to ensuring productive oversight by stakeholders, the courts, and political processes. Assessing how an agency explicates its use of science also illuminates whether the agency is making the best use of the available information, including internal studies by agency scientists. This topic will even provide preliminary information about how and when an agency elects to use science advisory boards, external peer review, or other intermediate mechanisms of scientific review as part of its rulemaking process."

I don't see how your research method can answer any of these questions.

What seems to be missing from your outline, yet is crucial for establishing a clear research strategy, is a clear definition of the problem. To give one obvious example, in Section A.1 you cite NAS and BPC as authorities for establishing the existence of "the problem," but they do not define "the problem" the same way. The NAS formaldehyde review scrupulously avoids clearly stating what the problem is, and the definitions in each of the general NAS risk assessment tomes tend to be different--sometimes subtly so, sometimes starkly. And the BPC views "the problem" very differently than you appear to do.

Here is a suggestion for a working definition of "the problem":

(A) Policy officials reaching into and attempting to influence or control the realm of science (i.e., what is).

(B) Scientific staff reaching into and attempting to influence or control the realm of policy (i.e., what ought to be).

The Obama Scientific Integrity memo lies squarely within this category, but of course it was issued before the administration had any experience with governing. Once can only imagine what its authors believe now. Could you interview them? Would they answer your questions candidly? How would you know? The BPC report lies mostly within this category because many of its members are people with extensive experience in governing. One suspects that before government service they thought (A) was "the problem" and now they think (B) is "the problem." Could you interview them? Would they answer your questions candidly? How would you know?

Your outline seems to be oriented toward making (A) more transparent. If that is your intent, then be clear about it and state up front that you are have no brief for making (B) more transparent. If that is right, then your search should be directed solely to purported examples of (A), but with much greater effort devoted to validating that they really were examples of (A) and not examples of (B) in disguise.

Subject: Re: Science in the Administrative Process
Posted by Richard B. Belzer on Wed, 23 Nov 2011 21:11:17 GMT
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Interagency coordination and transparency are competitors. The former cannot coexist with the latter. Case in point: Written communications between OMB and EPA on NAAQS rulemakings must be included in EPA's docket. The practical consequence is sensitive communications are shifted to the telephone. Therefore, to the extent that interagency coordination is a "solution" to "the problem" (which is still not clearly defined) it will reduce transparency rather than increase it.

There is an equilibrium (and low) level of transparency in interagency coordination. Any effort to increase transparency one place will be countered by a reduction elsewhere.

Subject: Re: Science in the Administrative Process
Posted by Richard B. Belzer on Wed, 23 Nov 2011 22:00:03 GMT
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From Peter Strauss: "[T]he proposal now is about the difference between what is conventionally described as risk/science assessment and risk/science management."

Perhaps, but version (B) of "the problem" (as I referred to it in my reply to Wendy's initial post) posits that there is a lot of policy lurking in "risk assessment." And we know this to be true, for the EPA staff has said so clearly:

Quote:EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks.

See EPA Office of the Science Advisor, "Examination of EPA Risk Assessment Principles and Practices," 2004, p. 13 (http://www.epa.gov/osainter/pdfs/ratf-final.pdf).

This means the EPA staff have a policy preference for erring on the side of overstating risk (just not "grossly") and an explicit determination NOT to estimate risk in an unbiased manner. This is a risk management choice embedded in a risk assessment. What justification does the EPA staff offer for this practice? It's because "EPA is a health and environmental protective agency." (Id.) Does Congress require this? EPA says so (pp. 13-16), but every example given concerns a Congressional risk management preference.

I've yet to see a single case in which Congress has directed EPA (or any other agency) to base decisions on biased estimates of risk. Consider the most famous (and perhaps most contentious) of these directives -- the requirement to set criteria air pollutant standards that "protect public health with an adequate margin of safety" without regard to cost per Whitman v. American Trucking. Does the CAA direct EPA to estimate health risk in a biased manner? No. In fact, it forbids this. Section 108(a)(2) requires that air pollution criteria "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities."

Accurate is a synonym for unbiased.

Subject: Re: Science in the Administrative Process
Posted by Susan Dudley (ACUS) on Fri, 25 Nov 2011 18:15:58 GMT
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Thanks for your quick response, Wendy. I don't think noting the distinction between science and policy judgment in the introduction will be sufficient.

I appreciate that it is difficult to separate science from policy, but that should encourage extra vigilance throughout the study, in identifying issues, conducting research, and offering recommendations. Richard Belzer (in post #43) offers a useful classification of the problem into 2 types: A) where policy officials attempt to influence the realm of science and B) where scientists attempt to influence the realm of policy.

Section I of the proposed outline highlights several key issues without mentioning problem type B, despite the BPC's conclusion that the "tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today" (BPC, 11).

Without recognizing the policy nature of many of these choices, issue I.B of the outline, for example, ("continuing challenges in protecting the scientific independence of government scientists and protecting against the politicization of science") may serve to reinforce the blurring of the line between science and policy by labeling as "politicizing" disputes over policy choices. Using Belzer's classification, you seem to presume the problem is A, and by doing so may exacerbate B. This is important, because according to the BPC report, "some disputes over the 'politicization' of science [Belzer's type A problem] actually arise over differences about policy choices that science can inform, but not determine." (BPC, 4)

Without a clearer distinction between what science can inform but not determine, issue I.C (asserting that science advisors are under-utilized) also seems overly broad. Note that BPC recommended that "scientific advisory panels should not be asked to recommend specific regulatory policies."(BPC, 5)

Subject: Follow-up to Dudley post dated November 25
Posted by Richard B. Belzer on Fri, 25 Nov 2011 20:47:45 GMT
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Wendy,

Greater reliance on science advisors might be a good remedy for Type A of the problem, but it's a dubious remedy at best for the Type B version. Here's a great example, one that I bet Susan

remembers all too well.

After EPA Administration Johnson selected 0.075 ppm for the ozone NAAQS in 2008, CASAC was mighty unhappy. The committee sent him an unsolicited letter containing, among other things, the following sentence:

"It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations."

See http://yosemite.epa.gov/sab/sabproduct.nsf/4AF87643243312888 52574250069E494/$File/EPA-CASAC-08-009-unsigned.pdf

This is a clear example of scientists attempting to reach into and influence or control the realm of policy. CASAC's statement is demonstrably false becauae there is no conceivable scientific definition of an "adequate" margin of safety. CASAC was expressing its consensus policy opinion in an extraordinarily disingenuous (though perhaps unwittingly transparent) way.

Each member of CASAC was entitled to have (and express) a view about policy. But CASAC was never entitled to misrepresent its policy views as science. Tragically, by making such a brazen claim of scientific authority, CASAC gravely damaged its own credibility as a scientific peer review body.

It is impossible now to read any of CASAC's reports and discern where its scientific review ends and its policy advocacy begins. EPA Administrators who have different policy views now must risk "interfering with science" to reclaim the authority delegated to them by Congress. EPA Administrators who agree with CASAC on policy face no such political challenge; they can disingenuously claim that they are merely upholding science.

This is why the selection of CASAC members (and peer reviewers generally) has become so controversial. The ability to choose the "scientists" is tantamount to choosing what policy advice to receive.

And this gives us a new Type C version of the problem: policy officials abdicating their statutory authority (and responsibility) to make policy decisions by hiding behind "science"--I.e., allowing scientists to reach into and control policy decisions because it is politically expedient.

Subject: Re: Follow-up to Dudley post dated November 25
Posted by Wendy Wagner (ACUS) on Mon, 28 Nov 2011 18:35:12 GMT
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Rick and Susan,

Thank you for your comments. I think we've fallen a bit off track with respect to the focus of this study, however. The intent of this first, general study is to explore how well the agencies explicate the role that science plays in regulatory decisions (e.g., literature reviews, how they weight studies, the processes they use for analyzing the relevant literature, external oversight

mechanisms, etc.; see the list of questions in part IIC). This focus on how well the agencies explicate science is by no means an easy job, but it is a whole lot easier methodologically than trying to identify why there may sometimes be a lack of transparency or blurring of science and policy (e.g., Rick's hypotheses a through c, plus many other possible causes, such as agency staff inadvertence and even incoherence). Remember too that this study is likely the first of likely many studies on regulatory science. Others from ACUS or outside of the government can later explore why the agencies might not explicate the role of science well in some settings, if there are problems with this first-level explication. Subsequent investigators can also study the science advisory process in detail (e.g., selection of members, points of controversy) as well as the costs and benefits of smoother interagency coordination on regulatory science.

Susan requests a more elaborate examination of some of the issues listed in Section I; but this section is not the focus of the study. Section II describes the focus of the study. Section I provides only background and is intended to offer an impressionistic sense of the larger science-policy landscape within which this narrow study is situated.

For purposes of the study, I will interview staff not only in the four agencies under investigation, but also staff in OSTP, OMB, NAS, and a range of stakeholders that include industry and public interest groups. Rick is correct that OMB, as well as these other staff, are important resources for the study. The list of interviewees should have been included in the outline; I apologize for this omission.

Thanks again for your comments. All the best, Wendy

Subject: Re: Science in the Administrative Process
Posted by Jamie Conrad on Mon, 05 Dec 2011 17:41:01 GMT
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Wendy

You have done a great job refocusing this initial ACUS study of science in the administrative process--not only is the scope a lot narrower than what you initially proposed in May, but you're addressing an issue that is centrally important both in its own right and, as you correctly note, for its ability to shed light on other important issues. The NAS Formaldehyde report and the White House scientific integrity memoranda do highlight a fundamental and widespread problem: agencies often do not clearly explain how they are using science. On the other hand, if they were clearer they would, among other things, make it easier for external entities to evaluate and police that usage. Of the following observations and suggestions, some are directed toward improving your proposal and others are intended to reinforce what you have already said. These comments derive primarily from your outline, but also reflect some prior posts in this forum.

1. Can you do this alone?

Much as I agree with your choice of issue, I have some reservations about the ability of your proposed method to generate really informed and reliable findings regarding the adequacy of

agency explanations of their use of science. I know you have a BS in Biology and have toiled in regulatory-scientific vineyard for your whole career. But the scope of your study is essentially a broader version of what the NAS Formaldehyde panel took it upon itself to do: critiquing how well agencies explain their scientific reasoning. I am concerned that one would need to be, or have access to, a scientist with some qualifications in the relevant field to do this well and feel confident that you were not being snowed by an agency that says it's doing a good job. (In many cases, agencies have guidance for various types of analyses and say they follow them. Serious claims are often made that they don't, and adjudicating these claims can require sophisticated expertise.) I'm not seeking to torpedo the project, only to raise the issue for further consideration.

2. Information gathering processes

In your outline, you note that a clearer statement of how an agency used science "provide[s] a more accessible view of what research has been done and what hasn't" and "invites a broader range of stakeholders into the process." In your post #37, you also highlight the information-gathering process that EPA uses at the commencement of each NAAQS revision. The National Academy of Sciences (BEST, at least) generally begins each new study with a day or half-day open session where stakeholders are invited to engage with panelists to discuss the state of the relevant science, including the major unanswered questions and most significant work to date. I would urge you to look carefully to see whether and how agencies use some sort of process like this at the outset of an initiative to make maximum use of external expertise and to clarify issues and questions as fully as possible. I'm attaching a comment that I filed with EPA's Science Advisory Board this summer in connection with its recent review of public participation processes. On pages 6 and 7-11, I describe a proposed process for this kind of early information-gathering. I have to think that it could generate enormous savings in time and improvements in quality.

3. Your "show your work" questions

I generally endorse the list of questions under Â§ II.C of your outline, and offer these additional comments:

- Overall. While it only applies to risk assessments conducted by EPA, probably the best single source of questions or considerations relevant to evaluating how well scientific assessments have been explained is the EPA Science Policy Council's Risk Characterization Handbook. Here's a link:

http://www.epa.gov/spc/pdfs/rchandbk.pdf

- d. "How the agency then used the relevant studies and weighted them?" I think this question warrants some unpacking. The central issue is whether the agency has articulated, in the words of the NAS, (i) "clear and concise statements of criteria used to exclude, include, and advance studies," involving "standardized approaches that are clearly formulated and based on the type of research," and (ii) "rationales for the selection of studies" that involve "rigorous and systematic coverage of the various determinants of weight of evidence." In each case, two things are at issue: (i) has the agency stated a clear decision framework, and (ii) has the agency actually explained how it applied that framework?

- e. "How the agency incorporated (or at least discussed) applicable, cutting edge methods and technologies or other bodies of evidence that interface with regulatory decisions?" This is important, because I think agencies are generally lagging indicators of scientific progress. Here or elsewhere, you should ask whether the agency has considered competing models and hypotheses. For example, probably the single greatest source of delay in EPA's evaluation of the carcinogenicity of chemicals, including formaldehyde, dioxin, and chromium VI, has been EPA's dismissal of nonlinear mechanisms of action--which the NAS or SAB has then criticized, leading to additional rounds of analysis and review.

- f. "The timing of the agency's assessment of the science in light of the policymaking features of the decision." A related timing question is whether the agency has constructed its timetable to take advantage of privately-funded research that addresses important questions or uncertainties. I am well aware that this sort of work is commonly viewed as being conducted to "manufacture uncertainty." However, in my experience companies have been spending great sums of money to conduct tests pursuant to agency test guidelines and GLP rules aimed at answering key questions. In the absence of a public health emergency or reason to doubt the legitimacy of the outside work, and assuming that work is being done with reasonable dispatch, for an agency not to take it into account suggests to many that it had a preconceived outcome that it did not want upset by potentially inconsistent findings.

Some other potential questions:

- Has the agency explained whether it has used the best available science? E.O. 13563 says: "Our regulatory system . . . must be based on the best available science." As you note in post #34, clearer explication should make it easier to evaluate whether this is happening.

- Has the agency identified and discussed the major uncertainties in its analysis and their potential effect on its conclusions? See EPA Risk Characterization Handbook at 15-16.

- Has the agency identified and provided rationales for its use of judgments (e.g., assumptions and defaults)? See OMB's Updated Principles for Risk Analysis (2007) at 8 (available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb /memoranda/fy2007/m07-24.pdf)

- Has the agency consulted with outside sources of expertise at the outset of the effort and at other appropriate junctures? See my point about "information gathering processes" above.

4. "Politicization"

I am glad that Peter has flagged (his posts # 36 & 39) and you've recognized (your post #40) the need to encompass within "politicization" the ability of senior career staff (rather than only political appointees) to suppress or misrepresent the scientific work of the staff they supervise. By virtue of their authority and longevity (in contrast with politicals, who they can outlast), senior career staff can have enormous influence on agency scientific processes and positions.

It is also important to recognize, as the BPC report and Susan Dudley (post #47) have noted, that some "politicization" actually reflects disagreement over policy choices that our system charges political appointees with making.

5. Future work

I like your list of "other issues that deserve attention in the future" (Â§ I). Some observations:

- There is a lot of concern about the competency with which agencies use science in various settings. ("Transparency" ought to be addressed in this study, though, right?)

- There is a great deal of variation among and even within agencies regarding their use of review processes. Use of contractors to organize panels (thus evading FACA and ethics rules) is a chief problem; inconsistent application of ethics rules is another.

- I agree that there is a discouragingly low level of cross-fertilization and coordination among agencies on projects and methods.

- I still am not clear what distinction you are making between "science-advisors" and "advisory boards"--the latter seem to me a subset of the former.

Best,

Jamie

File Attachments

1) SAB Public Involvement Comments.pdf, downloaded 62427 times

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Subject: Re: Science in the Administrative Process
Posted by Wendy Wagner (ACUS) on Fri, 09 Dec 2011 20:12:49 GMT
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Jamie,

Thank for your comments. They are very helpful. I agree that, even with considerable narrowing, the study is still relatively ambitious, although I do not believe it is as ambitious as you suggest. The study will examine the processes and manner by which the agencies explain how science informed their regulatory decisions. Precisely because I am not a NAS panel w/ 2-3 years to study how the EPA handled one individual toxic substance, I cannot begin to review the substance of the agencies' analyses. However, I can judge whether agencies are generally offering some accessible/coherent-sounding explanations for how they reviewed the literature, weighed the uncertainty, etc. within categories of regulatory programs. Your questions in #3 at first blush seem fall into that "did the agency explain this or that?" category, but many of your questions (e.g., whether the agency has stated a clear decision framework) are much more substantive and detailed than I believe can be addressed in this initial study. More to the point, I worry that these more specific questions will require mastery of the intricate details of individual rules and ultimately explode the study into one that is far more extensive than originally envisioned. Such detailed inquiry also requires a high level of scientific sophistication and a level of expertise that you rightly suggest I lack (although I do have a little more scientific education

than you suggest -- a masters from Yale and the start of a PhD at U. of Virginia in envtl. sciences.). So I will do my best to consider these questions and agree they are important, but it is likely that most will have to await a subsequent study. In contrast, your BEST suggestion in part 2 of your post is exactly the kind of innovation that I can use for this study, so please pass along other similar suggestions as they come to you.

In response to your question about "science advisors" vs. "advisory boards" (in Part 5), for the former I was referring to the official person in some agencies who is designated as a "science advisor" (a position that is usually but not always appointed). Agencies like FDA and EPA have this science advisor position. There was even a science advisor to the AG for a while. This strikes me as an interesting innovation that may be worth studying in the future. Imagine how such a position could improve interagency coordination/communication, for example, if OSTP convened regular meetings of the agencies' science advisors. Regrettably, though, this feature is beyond the scope of my study; I simply intend to flag it for future research.

Again, thanks for your questions and suggestions. They are very useful in sharpening and refining the study's approach and goals. All the best, Wendy

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Subject: Re: Science in the Administrative Process
Posted by pldelacruz on Thu, 15 Dec 2011 17:10:31 GMT
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Wendy,

I very much appreciate your work on this important topic and the ability to read through the forum discussion. Comments are attached and I would be happy to discuss them or respond to any questions they might raise.

Thanks,
Peter

File Attachments
1) SIRC - ACUS Science in Admin Process 2011-12-15.pdf, downloaded 62726 times

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Subject: Re: Science in the Administrative Process
Posted by Reeve Bull (Staff) on Mon, 19 Dec 2011 16:21:55 GMT
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As of December 15 at 5:00 pm, the forum will no longer accept additional postings; it will, however, remain available in a "read only" format to allow interested users to read the postings submitted during the meeting. Please direct any inquiries to Staff Counsel Reeve T. Bull at rbull@acus.gov.
